510(k) Summary of Safety and Effectiveness

K020024

December 21, 2001

Submitted by: Artemis Medical, Inc.
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Device Name: Caris™ MiniTome Biopsy Instrument

Common Name: Biopsy Device

Classification Name: Instrument, Biopsy, 21 CFR §876.1075

Predicate Devices:

The Caris™ MiniTome Biopsy Instrument has the same general intended use, similar principles of operation, similar technological characteristics, and is substantially equivalent to the following predicate breast biopsy devices:

- Auto Suture ABBI System, by United States Surgical Corp. (#K983296, K963825)
- Site Select Breast Biopsy Device, by Imagyn Surgical (#K993936)
- BMI Mammotome, by Biopsys Medical (now Ethicon/Johnson & Johnson) (#K970565)
- Mammotome Hand Held Probe, by Ethicon Endo-Surgery (#K003297)
- En Bloc Biopsy System, by Neothermia (#K003190)
- Core Tissue Biopsy System, by Sanarus (#K003528)

Intended Use:

The Caris™ MiniTome Biopsy Instrument is indicated to provide breast tissue samples for histologic examination with partial or complete removal of an imaged abnormality.

The extent of an histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of an imaged abnormality does not predict the extent of removal of its histologic abnormality (e.g. malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

Device Description

The Caris™ MiniTome Biopsy Instrument is percutaneous device that removes a single intact biopsy sample. The Caris MiniTome is hand-held and may be used with common imaging modalities such as ultrasound and upright mammography. The system consists of three components: a localization needle, which also acts as a guidewire, the Caris™ MiniTome Biopsy Instrument, and a control module with flexible drive cable.

The Caris™ MiniTome Biopsy Instrument consists of a hand piece that has a stainless steel dissecting tip with a tungsten cutting wire loop. A guidewire extension runs through the central lumen of the device and attaches to a localization needle. The Caris™ MiniTome is placed over a localization needle, which is placed through or adjacent to the targeted tissue site. The localization needle has a braided mesh at the distal tip that is deployed to anchor the needle in place.

Once the MiniTome has been guided over the localization needle and is in position, the start button on the controller is pressed. This activates a controller sequence which first allows RF energy from a standard electrosurgical generator to pass through the cutting wire, deploys the cutting wire into a loop, rotates the distal tip and cutting wire a predefined number of rotations, then shuts off the RF current from the electrosurgical generator. Thus, the cutting loop automatically rotates through the desired excision zone to resect the tissue sample. An integral "Python" sleeve, which is a component of the Caris™ MiniTome, is manually advanced to encapsulate the excised specimen. Then the device and specimen is removed through the percutaneous incision.

Technological Characteristics

The Caris™ MiniTome Biopsy Instrument and its predicates have similar technological characteristics. The Caris™ MiniTome removes biopsy samples by electrosurgical cutting of the tissue. This is accomplished by using a standard, existing and available off-the-shelf electrosurgical generator in a cutting mode. In the ABBI device, the ABBI is fired by pulling the electrocautery trigger, which pulls a cautery snare and transects tissue with electrocautery. The Neothermia En Bloc biopsy device also uses electrosurgical cutting to biopsy the breast tissue.

Similar to the ABBI and Neothermia En Bloc systems, the Caris™ MiniTome Biopsy Instrument has an entrapment mechanism at the distal end of the probe to help encapsulate the biopsy tissue specimen.

The Caris™ MiniTome, ABBI, Neothermia, and Sanarus Core Biopsy Systems each remove a single biopsy tissue sample sufficient for histopathologic evaluation.

The Caris™ MiniTome does not introduce new technological issues.

Performance Data

Extensive performance testing has been completed with the device on a variety of animal and human tissues, including freshly excised human breast tissue. Data from these studies demonstrate that the Caris™ MiniTome Biopsy Instrument has been designed to operate at a power level and operation speed that will provide predictable breast biopsy samples, and that the MiniTome is effective at cutting and retrieving intact, un-fragmented biopsy specimens suitable for post-biopsy histopathologic evaluation.

Biocompatibility testing has been performed on the final product to demonstrate compliance with the ISO 10993 standard. The following tests were performed:

- Cytotoxicity (ISO Elution Method)
- In Vitro Hemolysis Study (Modified ASTM-Extraction Method)
- ISO Acute Intracutaneous Reactivity Study in the Rabbit
- ISO Sensitization Study in the Guinea Pig (Maximization Method)
- ISO Acute Systemic Toxicity Study in the Mouse
- Pyrogen Test (Rabbit)

The product passed all tests, demonstrating that the Caris MiniTome instrument is biocompatible.

Various electrical safety testing was conducted to demonstrate electrical safety of the Caris™ MiniTome Biopsy Instrument, including compliance to relevant sections of EN 60601-1-2 , EN60601-2-2 and EN60601-2-18. The electrical safety testing performed demonstrates that the Caris™ MiniTome is safe for its intended use.

Summary

The Caris™ MiniTome Biopsy Instrument is substantially equivalent in intended use, overall design, materials used, and operating characteristics compared to various predicate devices. Extensive performance and verification studies have demonstrated the ability of the Caris™ MiniTome to cut and capture suitable samples of excised tissue for histopathologic examination.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 0 3 2002

Artemis Medical, Inc.
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Hayward, California 94545

Re: K020024
Trade Name: Caris Minitome Biopsy Instrument
Regulation Number: 876.1075
Regulation Name: Gastroenterology/Urology Biopsy Instrument
Regulatory Class: II
Product Code: KNW
Dated: December 21, 2001
Received: January 3, 2002

Dear Dr. Abati:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number: K020024

Device Name:

Caris™ MiniTome Biopsy Instrument

Indication for Use:

The Caris™ MiniTome Biopsy Instrument is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. The instrument is intended to provide breast tissue for histologic examination with partial or complete removal of an imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of its histologic abnormality, e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

Miriam C Provost
(Division Sign-Off) (Optional Format 1-2-96)
Division of General, Restorative
and Neurological Devices

510(k) Number K020024